Summary of Safety and Effectiveness for the Reprocessed Ultrasonic Instruments

submitted by

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Contact Person: Mary Ann Barker
Device Trade Names: MediSISS™ Reprocessed Ultrasonic Surgical Instruments
Common Names: Reprocessed Ultrasonic Surgical Instruments
Classification Names: Instrument, Ultrasonic Surgical, Unclassified; Product Code: LFL; Regulatory Class: II

Identification of a Legally Marketed Predicate Device

The SISS d.b.a. MediSISS™ Reprocessed Ultrasonic Surgical Instruments are substantially equivalent to the devices as listed below:

Company	510(k) #
Ethicon Endo-Surgery (Ultracision)	K980099, K993054, and K010898
U.S.Surgical	K971861
Olympus Optical	K972114

They are also similar to the Reprocessed Ultrasonic Surgical Instruments reprocessed by SterilMed Corporation and legally marketed and distributed pursuant to *Reprocessed Harmonic Scalpels* 510(k) K012571 and likewise, Vanguard's 510(k) 022780 *Vanguard Reprocessed Ultrasonic Scalpel.*

Device Description

Reprocessed Ultrasonic Surgical Instruments consist of hand-manipulated devices, with or without rotation capability, with or without cutting ability.

The handpiece handles are connected to the distal end-effector by a narrow-diameter metal barrel or shaft. The distal end of the device consists of a scalpel with a variety of end configurations including Flat, Cutting, and Blunt or a combination of the same. The devices are designed to be inserted through an appropriately sized trocar sleeve or cannula or used to be used in open surgery. The end-effectors are usually operated by the handpiece handles. The handles may be designed to be suppressed and released to activate the instruments end-effector. Similarly the handle may incorporate a button or switch to activate the end-effectors.

The device's shaft may be designed to (depending on the device model and type) be rotated (up to 360°) either direction (by manipulating controls located on the handle.)

Intended Use

The SISS d.b.a. MediSISS™ Reprocessed Ultrasonic Surgical Instruments are intended for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel instruments. The instruments are used in general, pediatric, thoracic, gynecologic, urologic, and other open and endoscopic surgeries for the transection, dissection, and coagulation of tissue(s).

Summary of Technological Characteristics

The intended use and technological features of the reprocessed devices do not differ from the legally marketed predicate device(s). Both the reprocessed devices(s) and the predicate device(s) have the same materials and product design. There are no changes to the claims, intended use, clinical applications, patient populations, performance specifications, or methods of operation. The technological characteristics of the Reprocessed Ultrasonic Surgical Instruments are the same as those of the legally marketed predicate devices. In addition the SISS d.b.a. MediSISS™ manufacturing process includes 100 % visual and mechanical testing of all products prior to packaging, labeling, and sterilization.

Summary of Performance Data

The SISS d.b.a. MediSISS™ Reprocessed Ultrasonic Surgical Instruments comply with the following standards, practices, and guidance's:

Sterilization Validation and EO Residuals:

- ANSI/AAMI/ISO 11135-1994, *Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization*

- ANSI/AAMI/ISO 10993-7:1995, *Biological Evaluation of Medical Devices—Part 7: Ethylene oxide sterilization residual.*

Cleaning Validation:

- AAMI RDS0TIR No. 12-1994. *Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A guide for Device Manufactures. Association for the Advancement of Medical Instrumentation, Arlington, VA.Food and Drug Administration. 1996.*
- *Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance, Office of Device Evaluation. FDA, Washington, D.C.*

Cleaning, sterilization, packaging validations, and visual/mechanical testing demonstrate that the devices are equivalent and continue to be safe and effective for their intended use.

SISS d.b.a. MediSISS™ Reprocessed Ultrasonic Surgical Instruments undergo mechanical testing to demonstrate that the parts do not change in function. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging.

Conclusion

Since the SISS d.b.a. MediSISS™ Reprocessed Ultrasonic Surgical Instruments meet the requirements of the stated standards and embody technological characteristics identical to the predicate device, we believe the device is safe and effective and performs as well as or better than the predicate device. The SISS d.b.a. MediSISS™ Reprocessed Ultrasonic Surgical Instruments will be reprocessed per specifications, good manufacturing practices, and QSR (Quality System Regulations) that ensure the device is safe and effective for its intended use.

In Accordance with the Federal Food, Drug, and cosmetic Act, 21 CFR Part 807, and based on the 510(k) "Substantial Equivalence" Decision Making Process Chart and the information provided in this premarket notification, SISS d.b.a. MediSISS™ concludes that the device(s)(Reprocessed Ultrasonic Instruments) are safe, effective, and substantially equivalent to the predicate devices as described herein.

This conclusion is based upon the SISS d.b.a. MediSISS™ Reprocessed Ultrasonic Surgical Instruments similarities in functional design, materials, indications for use, and methods of construction to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2004

Ms. Mary Ann Barker
Director of Quality Assurance
and Regulatory Affairs
MediSISS
723 Curtis Court
P.O. Box 2060
Sisters, Oregon 97759

Re: K030598
Trade/Device Name: MediSISS Reprocessed Ultrasonic Surgical Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: LFL
Dated: December 30, 2003
Received: December 31, 2003

Dear Ms. Barker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Page 1 of 1

510(k) Number (if known):_____

Device Name: SISS d.b.a. MediSISS™ Reprocessed Ultrasonic Surgical Instruments

Indications for Use:

The SISS d.b.a. MediSISS™ Reprocessed Ultrasonic Surgical Instruments are intended for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments can be used as an adjunct to or substitute for electrosurgery, lasers, and steel instruments. The instruments are used in general, pediatric, thoracic, gynecologic, urologic, and other open and endoscopic surgeries for the transection, dissection, and coagulation of tissue(s).

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K030598